

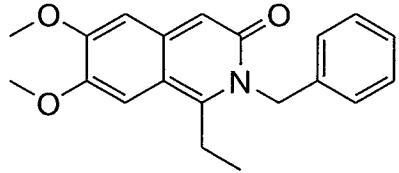
REMARKS

Claims 1-77 were originally filed. Claims 2-39, 41 and 44 were cancelled and Claims 1, 40, 42-43, 46 and 54-77 were amended in the previously submitted Preliminary Amendment. On receipt of this Office Action, Claims 1, 40, 42-43 and 45-77 were pending. Claim 1 is cancelled herein as being directed to non-elected subject matter and Claims 48, 50-53, 56-63, 66-70 and 72-76 are withdrawn from consideration as being directed to non-elected subject matter. Claims 40, 42-43, 45, 47 and 54-77 are amended herein (withdrawn Claims 56-63, 66-70 and 72-76 being amended as well in anticipation of the Examiner broadening the scope of the examination of the elected species). Claims 78-88 are newly added. The amendments to the Claims and new Claims 78-88 are fully supported in the Specification as originally filed and do not constitute new matter. Accordingly, reconsideration of the claimed subject matter is respectfully requested in view of the foregoing amendments and the following remarks.

Applicants reserve the right to pursue subject matter removed from the amended claims in a continuing application without prejudice

Elections and Restrictions

The Examiner acknowledged Applicants' election of Group II (Claims 40, 42-43, 45-52 and 54-77). The Examiner also acknowledged Applicants' election of the following compound:



i.e., 2-benzyl-1-ethyl-6,7-dimethoxy-2H-isoquinoline-3-one, as the species upon which the examination was based. The Examiner also acknowledged Applicants' election of the *in vivo* method of treating a mammal of Claim 45 and Applicants' election of inflammation as the single disclosed disease or disorder. In view of these elections, the Examiner withdrew Claim 1 and the portion of Claims 54-77 that are drawn to pharmaceutical compositions from further consideration as being drawn to non-elected subject matter. In addition, the Examiner withdrew Claims 48, 50-53, 56-63, 66-70 and 72-76 as being directed to non-elected species.

Specification

The Examiner rejected Claims 40, 42-43, 45-47, 49, 54-55, 64-65, 71 and 77 under 35 U.S.C. 112, ¶ 1, for lack of enablement. In particular, the Examiner contended that the specification, while being enabling for inhibition of SGK_a activity *in vitro* and for methods to assay markers associated with inflammation, does not reasonably provide enablement for a method to treat (which is defined by the specification to include preventing) inflammation or to treat any disorder or condition associated with hyperproliferation or to treat **any** disease (even those that are not associated with inflammation and/or angiogenesis). The Examiner noted that the Applicants have given the term "treating" a special definition which includes both prevention of a disease and treatment of pre-existing conditions. The Examiner specifically points out that Applicants have not provided any evidence to support a claim for the prevention of inflammation.

Applicants respectfully traverse this rejection in view of the above amendments to Claim 40 (from which Claims 42-43, 54-55, 64-64, 71 and 77 depend), Claim 45 (from which Claim 46 depends), and Claim 47 (from which Claims 48-53 depend). Although not acquiescing to the Examiner's reasons for this rejection, Claims 40, 45 and 47 are amended to further the allowance of this application. In particular, Claims 40 and 45 are amended to recite methods of treating a "pre-existing" disease or condition to further the allowance of the application. The Examiner's contention that these claims encompass methods of preventing a disease or condition is therefore no longer viable in view of these amendments.

Furthermore, Claim 40, which is now directed to a method of treating a mammal having a hyperproliferative disorder associated with SGK activity, which includes, e.g., cancer, inflammation and angiogenesis, by administering a compound of formula (I) capable of inhibiting SGK activity is clearly enabled by the specification. Assays are described in the specification which one skilled in the art could use to determine whether or not a compound of the invention is capable of inhibiting SGK activity. Given that SGK activity is well known to be associated with the etiology of hyperproliferative disorders, one skilled in the art would reasonably expect that a compound of the invention, if shown to be capable of inhibiting SGK activity by the assay described in the specification, would be useful in treating a hyperproliferative disorder associated with SGK activity. Accordingly, Applicants respectfully submit that amended Claim 40 (and dependent Claims 42-43, 54-55, 64-64, 71 and 77) is clearly enabled by the specification as originally filed under 35 U.S.C. 112, ¶ 1, and respectfully request that the rejection thereto be withdrawn.

With respect to Claim 45, the Examiner contended that it is not clear that the method of Claim 45 would be effective in treating **any** pre-existing disease or condition associated with hyperproliferation and cell survival. Claim 45 has been amended such that the compound of formula (I) utilized therein is capable of inhibiting the activity of SGK activity. Accordingly, undue experimentation would not be required to determine which compound of formula (I) would be efficacious in inhibiting SGK activity. As noted above, assays are described in the specification which one skilled in the art could easily employ to determine the ability of a compound of the invention to inhibit SGK activity. Such routine experimentation would not be considered undue. Accordingly, Applicants respectfully submit that amended Claim 45 (and dependent Claim 46) is clearly enabled by the specification as originally filed under 35 U.S.C. 112, ¶ 1, and respectfully request that the rejection thereto be withdrawn.

With respect to Claim 47, the Examiner contended that the Applicants have not enabled the treatment or prevention of **any** disease in which inflammation or angiogenesis is not involved (giving Claim 47 its broadest reasonable interpretation). Without acquiescing to the Examiner's contention, Applicants have amended Claim 47 to be directed to a method of inhibiting SGK activity within a mammalian cell wherein the method comprises administering to the cell a compound of the invention wherein the compound is capable of inhibiting the activity of SGK activity within the cell. In other words, this claim is now directed to the inhibition of a particular enzyme within a mammalian cell, as opposed to a method of treating a particular disease or condition. Given that SGK activity is well known as being associated with the etiology of hyperproliferative diseases, one of ordinary skill in the art would reasonably expect that compounds of the invention, having been shown to inhibit SGK activity *in vitro* and to inhibit cell proliferation in a cell-based assay, would be useful in inhibiting SGK activity within a mammalian cell. Accordingly, Applicants respectfully submit that Claim 47 (and dependent Claims 48-53) is clearly enabled by the specification as originally filed under 35 U.S.C. 112, ¶ 1, and respectfully request that the rejection thereto be withdrawn.

For the same reasons set forth above, Applicants respectfully submit that new Claims 78-88 are clearly enabled by the specification as originally filed. In particular, Claim 78 is directed a method of treating pre-existing inflammation or pre-existing angiogenesis in a mammal, wherein the inflammation and angiogenesis are both associated with SGK activity, by administering a compound of the invention having the capability of inhibiting SGK activity. One skilled in the art could easily determine whether or not a compound of the invention has the capability of inhibiting SGK activity by testing the compound in the *in vitro* assay described in

the specification. Such determination would not be considered undue considering the detailed description of the *in vitro* assay and the various cell-based assays described in the specification to determine the compounds' ability to reduce the symptoms of increased SGK activity (such as cell proliferation). Accordingly, Applicants respectfully submit that new Claims 78-88 are clearly enabled by the teachings of the specification.

In view of the foregoing amendments and remarks, Applicants respectfully submit that amended Claims 40, 42, 43, 45-47, 49, 54-55, 64-65, 71 and 77 and new Claims 78-88 are clearly enabled under 35 U.S.C. 112, ¶1, and respectfully request that they be allowed to issue forthwith. Such action is earnestly solicited at an early date.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Respectfully submitted,
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